

Medication Guide

XARTEMIS™ XR (ZAR-tem-iss) (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets, CII

XARTEMIS XR is:

- A strong prescription pain medicine that contains an opioid (narcotic) and the medicine acetaminophen. XARTEMIS XR is used to treat certain types of short term (acute) pain.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about XARTEMIS XR:

- **Get emergency help right away if you take too much XARTEMIS XR (overdose).** When you first start taking XARTEMIS XR, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Never give anyone else your XARTEMIS XR. They could die from taking it. Store XARTEMIS XR away from children and in a safe place to prevent stealing or abuse. Selling or giving away XARTEMIS XR is against the law.
- Get emergency help right away if you take more than 4,000 mg of acetaminophen in 1 day. Taking XARTEMIS XR with other products that contain acetaminophen can lead to serious liver problems and death.

Do not take XARTEMIS XR if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- allergy to acetaminophen or oxycodone.

Before taking XARTEMIS XR, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use during pregnancy can cause life-threatening withdrawal symptoms in your newborn baby if not recognized and treated.
- **breastfeeding.** XARTEMIS XR passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking XARTEMIS XR with certain other medicines can cause serious side effects.

When taking XARTEMIS XR:

- Do not change your dose. Take XARTEMIS XR exactly as prescribed by your healthcare provider.
- Take your prescribed dose every 12 hours, at the same time every day. If you miss a dose, take XARTEMIS XR as soon as possible, then take your next dose 12 hours later. If it is almost time for your next dose, skip the missed dose. Take your next dose at the regular time. Do not take more than your prescribed daily dose in 24 hours.
- Swallow XARTEMIS XR whole. Do not cut, break, chew, crush, dissolve, snort or inject XARTEMIS XR because this may cause you to overdose and die. You should not receive XARTEMIS XR through a nasogastric tube or gastric tube (stomach tube).
- Take XARTEMIS XR 1 tablet at a time. Do not pre-soak, lick, or wet the tablet before placing in your mouth. Take each XARTEMIS XR tablet with enough water to be sure that you swallow it completely as soon as you place it in your mouth.
- **Call your healthcare provider if XARTEMIS XR does not control your pain.**
- **If you have been taking XARTEMIS XR for more than a few days, do not stop taking it without talking to your healthcare provider.**
- After you stop taking XARTEMIS XR, flush any unused tablets down the toilet.

While taking XARTEMIS XR:

- Do not drive or operate heavy machinery, until you know how XARTEMIS XR affects you. XARTEMIS XR can make you sleepy, dizzy, or lightheaded.
- Do not drink alcohol.
- Do not take other products that contain acetaminophen while taking XARTEMIS XR.

The possible side effects of XARTEMIS XR are:

- nausea, dizziness, headache, vomiting, constipation, sleepiness. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, low blood pressure when changing positions, or you are feeling faint.
- rash with hives, sores in your mouth or eyes, or your skin blisters and peels.

These are not all the possible side effects of XARTEMIS XR. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

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